

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/781,464	MADHYASTHA, SRINIVASA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/1/07.
2. ☒ The allowed claim(s) is/are 42-48 and 50-53.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 42-53 are pending.

Applicant's amendment filed June 1, 2007 is acknowledged, and applicants' response has been fully considered. Claims 42, 43, 47 and 53 have been amended. Therefore, claims 42-53 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claim 43 is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 5 in the amendment filed June 1, 2007.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 42-53 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 5-6 in the amendment filed June 1, 2007.

### **Examiner's Amendment**

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian R. Dorn on August 16, 2007.

#### **Examiner's Amendment to the Claims:**

Cancel claim 49.

Claims 42, 46, 47, 50 and 53 have been amended as follows:

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42. (Currently amended) A medical device comprising a composition, wherein said composition comprises an effective amount of (a) ovotransferrin, protamine sulfate, and ethylenediaminetetraacetic acid (EDTA) or (b) ovotransferrin and protamine sulfate, wherein the effective amount of (a) or (b) inhibits formation of a bacterial biofilm.

46. (Currently amended) The medical device of claim 43, wherein the tubing is selected from the group consisting of intravenous ~~tubing~~ tube, breathing ~~tubing~~ tube, dental water line, dental drain tube, and feeding tube.

47. (Currently amended) An article for inhibiting formation of bacterial biofilm comprising a coating and a medical device wherein said coating comprises: an effective amount of (a) ovotransferrin, protamine sulfate, and ethylenediaminetetraacetic acid (EDTA) or (b) ovotransferrin and protamine sulfate, wherein the effective amount of (a) or (b) inhibits formation of a bacterial biofilm.

50. (Currently amended) The article of claim 49 ~~47~~, wherein the medical device is selected from the group consisting of a tubing, a catheter, a pacemaker, a prosthetic heart valve, a prosthetic joint, a voice prosthetic device, a contact lens, a vascular graft, a vascular catheter port, a wound drain tube, a hydrocephalus shunt, a heart valve, a heart assist device, a pacemaker capsule, an incontinence device, a penile implant, a joint replacement, a cannula, an elastomer, a hydrogel, a surgical instrument, a dental instrument, a fabric, an adhesive, a bandage, an orthopedic implant, and an intrauterine device.

53. (Currently amended) The article of claim 50, wherein the tubing is selected from the group consisting of intravenous ~~tubing~~ tube, breathing tube, dental water line, dental drain tube, and feeding tube.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be related to the claimed invention. Willcox *et al.* (CA 2, 284,364) disclose an antimicrobial agent such as lactoferrin is used to coat a surface of a biomedical device such as stents, implants, catheters and ophthalmic lenses, and wherein the surface on the biomedical device is a polymer of ethylene or propylene, polyurethanes, polyesters and mixtures thereof, or silicones containing hydrogels. Tomita *et al.* (EP 629347) disclose an antimicrobial agent comprising lactoferrin hydrolysates, one or more antimicrobial peptides from lactoferrin; and one

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of more compounds selected from the group consisting of metal-chelating protein (e.g., lactoferrin, transferrin, conalbumin), tocopherol, EDTA or a salt thereof. The reference also teaches the antimicrobial agent can be used for treatment of any products or materials thereof, e.g., dentifrices, diapers or others. Charter *et al.* (US 2002/0001582) discloses a fungicidal composition comprising one of more "active ingredients" or "fungicides" which is selected from the group of avidin, lysozyme, ovotransferrin, chicken immunoglobulins, chitosan, polylysine, protamine, nisin, EDTA, rosemary, cinnamaldehyde, allicin and eugenol (paragraph [0073]); and a method of treating plants, plant tissues and seeds that are infected with fungi, the method comprising contacting the plants, plant tissues and seeds with avidin in an effective amount to inhibiting fungi, and the composition may further comprise an effective amount of a compound selected from the group consisting of lysozyme, ovotransferrin, chicken immunoglobulins, chitosan, polylysine, protamine, nisin, EDTA, rosemary, cinnamaldehyde, allicin and eugenol. Johansen (WO 96/06532) discloses a bacteriocidal or fungicidal composition comprising a basic protein in combination with a cell-wall degrading enzyme or an oxidoreductase, where either protamine or protamine sulfate can be used as the basic protein. However, the four references either alone or combined do not teach a medical device comprising a composition having an effective amount of ovotransferrin, protamine sulfate and EDTA, or of ovotransferrin and protamine sulfate to inhibit the formation of a bacterial biofilm. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



**CHIH-MIN KAM**  
**PRIMARY EXAMINER**

CMK

August 16, 2007